

Notice of Allowability

Application No.

09/679,147

Applicant(s)

TODO ET AL.

Examiner

Anne Marie S. Wehbe

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/2/05.
2. ☒ The allowed claim(s) is/are 1, 7-9, 15, 16, 19-21, 23, 48, 49, 55, 58, 60 and 62.
3. ☒ The drawings filed on 05 October 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

Applicant's amendment and response received on 5/2/05 has been entered. Claims 2-6, 10-14, 17-18, 22, 24-47, 50-54, 56-57, 59, and 61 are canceled. Claims 1, 7-9, 15-16, 19-21, 23, 48-49, 55, 58, 60, and 62 are pending in the instant application.

The rejection of claims 1, 7-8, 15-16, 20-21, 23, 48-49, 55, 58, 60, and 62 under 35 U.S.C. 103(a) over Fong et al. in view of Sturmhoefel et al., and the rejection of claim 19 under 35 U.S.C. 103(a) over Fong et al. in view of Sturmhoefel et al. and further in view of Whitley et al. are both **withdrawn** in view of the evidence submitted by the applicants that the Sturmhoefel et al. reference, although bearing a publication date of October 1, 1999, was not actually mailed until October 4, 1999, such that it could not have been received by the public before October 5, 1999, applicant's priority date. The evidence submitted includes an email from Morgan Robinson, a representative of the AACR, the publisher of Cancer Research. The examiner also contacted Morgan Robinson by phone and verified that in fact no copy of the October 1, 1999 issue of Cancer Research was mailed before October 4, 1999, or was otherwise made available to the public, for instance by online publication. As such, applicant's argument that Sturmhoefel et al. does not qualify as prior art under 35 U.S.C. 102(a) is persuasive. Further, absent the teachings of Sturmhoefel et al., Fong et al. by itself, or as supplemented by Whitley et al. does not teach or suggest expressing B7-1-Ig or B7-2-Ig using a recombinant Herpes Simplex Virus vector.

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It is further noted that while plasmid constructs encoding B7-1-Ig or B7-2-Ig were reported in the prior art, the prior art only suggests expressing B7-1-Ig or B7-2-Ig in tissue culture cells *in vitro*, and does not teach or provide motivation for administering nucleic acids encoding B7-1-Ig or B7-2-Ig *in vivo* or for expressing B7-1-Ig or B7-2-Ig using HSV vectors. Further, Fong et al., while teaching HSV vectors encoding wild type B7 molecules useful for *in vivo* administration to treat cancer, does not teach or suggest using a soluble form of B7 or specifically B7-1-Ig or B7-2-Ig. As such, claims 1, 7-9, 15-16, 19-21, 23, 48-49, 55, 58, 60, and 62 are considered free of the prior art of record and allowable at this time.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen Bent on 7/19/05.

The application has been amended as follows:

1. On page 1, line 1 of the specification, the following paragraph has been inserted:

This application claims benefit of priority to provisional United States application 60/157,787, filed on October 5, 1999.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal flourish extending to the right.